The following corrections or additions to the January 15, 1997 list were made in April, 1997

New Approvals

ANADA No.: 200-061

Pioneer Product:	101-479
Trade Name:	Flunixin Meglumine
Ingredients:	Flunixin meglumine
Sponsor:	AgriLabs
Approval Date:	09/11/96
Status:	Prescription Only
Route:	Intravenous or intramuscular
Species:	Equine
Drug Form:	Liquid (solution)
Concentration:	50 mg/mL
Indications:	For the alleviation of inflammation and pain associated with musculoskeletal disorders in horses. It is also recommended for the alleviation of visceral pain associated with colic in horses.

21CFR 522.970 (FR 04/28/97. Page 22888)

ANADA No.: 200-191

Pioneer Product:	092-523
Trade Name:	Gentasol
Ingredients:	Gentamicin sulfate
Sponsor:	Med-Pharmex, Inc.
Approval Date:	03/24/97
Status:	Over-the-counter
Route:	Dip
Species:	Turkey eggs
Drug Form:	Liquid (solution)
Concentration:	50 mg/mL
Indications:	For the reduction or elimination of the following organisms from turkey hatching eggs: *Arizona hinshawii* (paracolon), *Salmonella st. paul*, *Mycoplasma meleagridis.*
Tolerance:	Not established.
Withdrawal:	Not established.

21CFR 529.1044(b) (FR 04/28/97. Page 22888)

ANADA No.: 200-026

Pioneer Product:	008-622
Trade Name:	Oxytetracycline HCl-343
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	PennField Oil Company
Approval Date:	03/13/97
Status:	Over-the-counter
Route:	Oral
Species:	Bovine, ovine, porcine, avian (chickens, turkeys)
Drug Form:	Powder
Concentration:	102.4 g/packet
Indications:	Calves, beef cattle and nonlactating dairy cattle: for the treatment and control of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*. Swine: for the control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella cholerasuis*, bacterial pneumonia caused by *Pasteurella multocida*; and for breeding swine, leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*. Sheep: for the control and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*. Chickens: for the control and treatment of infectious synovitis caused by *Mycoplasma synoviae*; chronic respiratory disease (CRD) and air-sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*; fowl cholera caused by *Pasteurella multocida*. Turkeys: for the control and treatment of hexamitiasis caused by *Hexamita meleagridis*; infectious synovitis caused by *Mycoplasma synoviae*; growing turkeys-complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).
Tolerance:	21CFR 556.500: 6 ppm in liver, 2 ppm in muscle, 12 ppm in kidney, and 12 ppm in fat.
Withdrawal:	Cattle, sheep, swine, chickens, turkeys: 5 days.

21CFR 520.1660d (FR 04/30/97. Page 23356)

ANADA No.: 200-192

Pioneer Product:	031-205
Trade Name:	Sulfadimethoxine 12.5% Oral Solution
Ingredients:	Sulfadimethoxine B.P.
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	03/24/97
Status:	Over-the-counter
Route:	Oral
Species:	Bovine (dairy calves, dairy heifers and beef cattle), avian (chickens, turkeys)
Drug Form:	Liquid (solution)
Concentration:	125 mg/mL
Indications:	Broiler and replacement chickens: for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza. Meat-producing turkeys: for the treatment of disease outbreaks of coccidiosis and fowl cholera. Dairy calves, dairy heifers and beef cattle: for the treatment of shipping fever complex, and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sufadimethoxine.
Tolerance:	21CFR 556.640: 0.1 ppm (negligible residue) in uncooked edible tissues of chickens, turkeys, and cattle; 0.01 ppm in milk (negligible residue).
Withdrawal:	Chickens and turkeys: 5 days; cattle: 7 days.

21CFR 520.2220a (FR 04/30/97. Page 23356)

ANADA No.: 200-178

Pioneer Product: 127-892
Trade Name: Amikacin Sulfate Injection
Ingredients: Amikacin sulfate USP
Sponsor: Phoenix Scientific, Inc.
Approval Date: 03/14/97
Status: Prescription Only
Route: Subcutaneous or intramuscular
Species: Canine
Drug Form: Liquid (solution)
Concentration: 50 mg/mL
Indications: For the treatment of the following conditions in dogs: genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* sp. Skin and soft tissue infections caused by susceptible strains of *Pseudomonas* sp. and *Escherichia coli.*

21CFR 522.56 (FR 04/30/97. Page 23357)

ANADA No.: 200-181

Pioneer Product: 127-892
Trade Name: Amikacin Sulfate Solution
Ingredients: Amikacin sulfate
Sponsor: Phoenix Scientific, Inc.
Approval Date: 03/18/97
Status: Prescription Only
Route: Intrauterine
Species: Equine
Drug Form: Liquid (solution)
Concentration: 250 mg/mL
Indications: For the treatment of uterine infections (endometritis, metritis, and pyometra) in mares, when caused by susceptible organisms including *Escherichia coli, Pseudomonas* sp., and *Klebsiella* sp.

21CFR 529.50 (FR 04/30/97. Page 23357)

ANADA No.: 200-177

Pioneer Product: 041-245
Trade Name: Sulfadimethoxine Injection 40%
Ingredients: Sulfadimethoxine
Sponsor: Phoenix Scientific, Inc.
Approval Date: 03/13/97
Status: Prescription Only
Route: Intravenous
Species: Bovine
Drug Form: Liquid
Concentration: 400 mg/mL
Indications: For the treatment of bovine respiratory disease complex (shipping fever complex) and bacterial pneumonitis associated with *Pasteurella* spp. sensitive to sulfadimethoxine; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum* (*Sphaerophorus necrophorus*) sensitive to sulfadimethoxine.
Tolerance: 21CFR 556.640: 0.1 ppm (negligible residue) in uncooked edible tissues of cattle; 0.01 ppm (negligible residue) in milk.
Withdrawal: 5 days.
Milk Discard: 60 hours (5 milkings)

21CFR 522.2220 (FR 04/29/97. Page 23128)

Supplemental Approvals

NADA No.: 039-417

Trade Name:	Deccox
Ingredients:	Decoquinate
Sponsor:	Rhone-Poulenc, Inc.
Approval Date:	03/07/97
Status:	Over-the-counter
Route:	Oral
Species:	Bovine, ovine, caprine, avian (broiler chickens)
Drug Form:	Type A medicated article to make a Type B feeds to make Type C medicated feed for cattle, sheep, and goats.
Concentration:	Type A: 6%; Type B: 0.06 to 0.6%; Type C: 0.0015 to 0.059%.
Indications:	Cattle: for the prevention of coccidiosis in ruminating and nonruminating calves (including veal calves) and cattle caused by *Eimeria bovis* and *E.zurnii*. Young sheep: for the prevention of coccidiosis caused by *Eimeria ovinoidalis*, *E.parva*, *E.bakuensis, E.crandallis*. Young goats: for the prevention of coccidiosis caused by *Eimeria christenseni, E. ninakohlyakimovae*.
Tolerance:	21CFR 556.170: 2 ppm in tissues other than skeletal muscle and 1 ppm in skeletal muscle of chickens, cattle, and goats.

This supplemental application provides for certain corrections to the Code of Federal Register (CFR) listing for decoquinate. A revised Blue Bird labeling for sheep, goats, and calves was also submitted under this application.

21CFR 558.195 (FR 04/29/97. Page 23128)

Actions Taken by FDA Center for Veterinary Medicine

Change of Sponsor

NADA No.: 140-915

From Ciba-Geigy Animal Health, Ciba-Geigy Corp. to:
Novartis Animal Health US, Inc.
P.O. Box 18300, Greensboro, NC 27419-8300
Drug labeler code: 058198

NADA No.: 141-026

From Ciba-Geigy Animal Health, Ciba-Geigy Corp. to:
Novartis Animal Health US, Inc.
P.O. Box 18300, Greensboro, NC 27419-8300
Drug labeler code: 058198

NADA No.: 141-035

From Ciba-Geigy Animal Health, Ciba-Geigy Corp. to:
Novartis Animal Health US, Inc.
P.O. Box 18300, Greensboro, NC 27419-8300
Drug labeler code: 058198

ANADA No.: 200-042

From Phoenix Pharmaceutical, Inc. to:
Phoenix Scientific, Inc.
Drug labeler code: 059130

Suitability Petition Action

Number.:	97P-0072 CP1
Sponsor:	VetrePharm Research, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, Butequineâ Paste (phenylbutazone paste) which differs from the pioneer product, Butazolidin Paste, Coopers Animal Health, NADA 116-087 by the following characteristics: Butequineâ Paste: 20 g of phenylbutazone per 60 mL syringe of paste (1 g/3 mL). Butazolidin Paste (pioneer): 12 g of phenylbutazone per 60 g syringe of paste (1g /5 g). The dosage (1-2 g of phenylbutazone/500 lbs body weight) is the same in both products. However, in the generic product, the dosage would be given as 3-6 mL as opposed to 5-10 g of the pioneer product.
Action:	Approved on 04/11/97.

Issue of a Patent

NADA 140-988	Patent No. 5,607,696	Expiration date: 02/20/2015

Correction of a Final Rule

The Final rule published in the Federal Register of July 10, 1996, (Green Book update of August, 1996) concerning the approval of a supplemental application for ANADA 200-008 is corrected to reflect that the supplemental approval was granted 3 years marketing exclusivity for the new use. The rule also failed to specify that only Boehringer Ingelheim's oxytetracycline injection is approved for subcutaneous use in cattle.

The following five supplemental NADA applications were approved on July, 1996 and published in the August update of the Green Book: 48-761, 92-286, 92-287, 46-699, 48-480, and 135-935. Certain limitations were not included in the document. These limitations are: "do not feed ducks producing eggs for human consumption"; "feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb/day"; the phrase "cattle (under 700 lb)" must be replaced by "beef cattle".

Correction to the January 1, 1997 list of the Green Book

- NADA 128-409: the expiration date for patent No. 4199569 is 10/03/97.

- NADAs 042-489, 098-156, 118-874, 127-825, and 127-826: the withdrawal effective date is 04/07/97.